

**R E M A R K S**

Claims 55-74 are currently pending in the present application. In the instant Office Action, the Examiner raised a number of issues, which are set forth by number in the order they are herein addressed:

- 1) Claims 55, 56, 58 and 64 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Magill (U.S. Patent No. 1,251,258); and
- 2) Claims 67-74 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Peterson *et al.* (U.S. Patent No. 5,730,777) in view of Csete *et al.* (U.S. Patent No. 6,184,035).

Applicants thank the Examiner for indicating that Claims 57, 59-63, 65 and 66 would be allowable if rewritten in independent form. In addition, Applicants hereby amends Claim 67 and cancels Claim 74, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments. Applicants reserve the right to prosecute the original, similar, or broader claims in one or more future application(s). These amendments do not introduce new matter and are not intended to narrow the scope of any of the claims within the meaning of *Festo*.<sup>1</sup>

**1) The Claims Are Novel**

The Examiner has rejected Claims 55, 56, 58 and 64 under 35 U.S.C. § 102(b) as allegedly anticipated by Magill (U.S. Patent No. 1,251,258). The Examiner states that Magill discloses methods comprising providing a device with:

a means for evacuating said isolated environment (9), [and] a means (13) for refilling said isolated environment ... [as well as methods comprising] evacuating any gas within said isolated environment (page 1, lines 69-80) by using said means for evacuating (9) (Office Action pages 2-4).

Applicants respectfully disagree that Magill anticipates the claimed invention. In contrast to the Examiner's assertions, the **means for evacuating** (9) and the **means for refilling** (13) of Magill *do not* act upon an isolated area comprising a surgical field or an injured area as required by the

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<sup>1</sup> *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002).

claims. Rather the invention of Magill provides means for evacuating and refilling an annular space (17) surrounding (but not including) an injured area as shown in Figures 1 and 2.

Specifically, Magill discloses that the:

bottom of the section 1 is provided with concentric flanges 14 and 15, whereby the space within the flange 14 constitutes a wound-closing chamber or cup 16, and the annular space 17 between the flanges constitutes a *suction channel* with which the apertures 13 connect. ... [t]he skin is sucked upwardly into the channel 17, so that the device is firmly anchored on the wounded part (Magill, page 1, lines 74-93, emphasis added).

As Magill does not teach all of the elements of the claimed invention, Applicants respectfully request that this rejection be withdrawn.

## **2) The Claims Are Nonobvious**

The Examiner has rejected Claims 67-74 under 35 U.S.C. § 103(a) as allegedly unpatentable over Peterson *et al.* (U.S. Patent No. 5,730,777) in view of Csete *et al.* (U.S. Patent No. 6,184,035).

Examiner states, that the device on Figure 2 [of Peterson] is capable for transporting said biological material. ... It would have been obvious to one of ordinary skill in the art at the time of the invention to use cells as a transplant material of Csete *et al.* ('035) in the method of Peterson *et al.* ('777) to provide oxygen-controlled isolated environment for intact functioning tissue or cells, as taught by Csete *et al.* ('035) (Office Action, pages 5 and 6).

Applicants must respectfully disagree that the claimed invention is obvious. Nonetheless, Applicants have amended Claim 67 and canceled Claim 74, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claim 67 to recite a "providing a device for maintaining and transporting transplant material," and to include step "c) transporting said transplant material in said device to a transplant operation site."

Support for this amendment is found for instance in canceled Claim 74, and in the description of the invention, which teaches the "CTE [controlled transport environment] is then transported to the site of the transplant operation" (Specification, at page 17, lines 14 and 15).

In contrast to the claimed invention, the combination of Peterson (directed to cell culture hoods) and Csete (directed to incubators for culturing cells) does not provide methods comprising **transporting** transport material in a controlled environment device, to a site of a transplant operation. In the first place, Peterson describes the bulky device of Figures 1-3 as a "*workbench* according to the invention wherein a housing comprising inner first chamber walls 1 encloses a first chamber 2 containing a gaseous atmosphere" (Peterson, at column 18, lines 42-45, emphasis added). Peterson adds "[t]he housing according to the invention may be produced of any *material known from the production of incubators and working benches such as stainless steel* (Peterson, at column 14, lines 46-48, emphasis added). Secondly, since the device of Peterson is described (by Peterson) as having characteristics of a stationary device, Applicants traverse the Examiner's unsubstantiated assertion that the Peterson device is capable of transporting transplant material. The Examiner is reminded that if he is "relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth the specific factual statements and explanation to support the finding (MPEP, 2144.04). As Peterson and Csete do not teach all of the elements of the claimed invention, Applicants respectfully request that this rejection be withdrawn.

**CONCLUSION**

Applicants respectfully request that a timely Notice of Allowance be issued in this case. However, should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourages the Examiner to call the undersigned collect.

Dated: April 26, 2005



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